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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/664,670

09/18/2003

R. Keith Frank

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7590

03/29/2005

THE DOW CHEMICAL COMPANY  
INTELLECTUAL PROPERTY SECTION  
P. O. BOX 1967  
MIDLAND, MI 48641-1967

EXAMINER

JONES, DAMERON

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/664,670

Applicant(s)

FRANK ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2004 and 16 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment file 10/15/04 wherein the specification was amended; claims 1, 5, and 6 were amended; and claim 4 was canceled. In addition, the Examiner acknowledges the amendment filed 12/16/04 wherein an abstract was submitted.

**Note:** Claims 1-3 and 5-11 are pending.

## **RESPONSE TO APPLICANT'S AMENDMENT**

2. The Applicant's arguments filed 10/15/04 to the rejection of claims 1-11 made by the Examiner under 35 USC 112 and/or double patenting have been fully considered and deemed persuasive-in-part for the following reason(s).

### **Double Patenting Rejection**

The provisional rejection of claims 1-3 and 5-11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 11, and 15-20 copending Application No. 10/031,792 is MAINTAINED for reasons of record in the office action mailed 8/6/04.

**Note:** It is duly noted that Applicant intends to respond to the double patenting rejection at which time the claims are allowable over the prior art.

### **112 Rejections**

The 112 rejections are WITHDRAWN for reasons of record in Applicant's response.

## NEW GROUNDS OF REJECTIONS

### 103 Rejection

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1- 3 and 5-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Lauffer et al (US Patent No. 6,652,835).

**Lauffer et al** disclose targeting multimeric imaging agents (contrast agents) that are useful for diagnostic imaging having two or more image enhancing moieties (IEMs) [see entire document, especially, abstract]. The IEM may be conjugated the chelating agents having one or more metal ion (column 212, lines 16-28). Various possible chelating agents may be used as the IEM moiety. One possible IEM is DOTA (1,4,7,10-tetraazacyclododecane-1,4,7,10-tetraacetic acid) [column 14, lines 9-10]. DOTA is encompassed by the instant invention when the variables of the instant invention have the following values:  $G = H$ ;  $Q = (CHR_5)pCO_2R$ ;  $R = H$ ;  $R_5 = H$ ;  $p = 1$ , and it is noted that at least tow of the sum of  $Q$  and  $Q_1$  is other than hydrogen. Also, it should be noted that Lauffer et al disclose DOTA labeled with gadolinium (column 14, lines 45-46). In addition, Lauffer et al disclose that the contrast agent may have tow or more target binding moieties (TBMs). The TBMs enable the contrast agent to bind to proteins and other targets (columns 14-15, bridging paragraph). The TBMs may be selected

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depending upon the target site desired. Possible TBMs include drugs, lipophilic/amphiphilic organic molecules, porphyrins, receptor ligands, steroids, lipids, hormones, peptides, oligonucleotides, or carbohydrates (column 16, lines 1-9). Pharmaceutical compositions comprising the compounds in combination with a carrier, adjuvant, vehicle, or excipient may be generated (column 30, lines 28-32). While Lauffer et al disclose various possible metals that may be attached to the targeting agents, the reference fails to specifically disclose the conjugation of the targeting agents to  $^{225}\text{Ac}$ . In addition, the reference does not disclose all possible combinations wherein a biological substance is conjugated to the contrast agent.

While Lauffer et al does not specifically disclose DOTP conjugated to actinium-225, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace one metal (transition metal such as gadolinium) with another because a skilled artisan would recognize that elements of the same chemical family would be expected to have similar/same chemical properties. Thus, the replacement of one metal with another would not drastically alter the chemical property of the overall complex. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to attach a group (i.e., Applicant's G group) off the DOTA (generating a DOTA derivative) because Lauffer et al disclose that the contrast agent has attached thereto two or more TBMs that when Applicant's variables  $r$ ,  $n$ ,  $m$ , and  $t$  are zero;  $Q_1$  is hydrogen and  $R_1 = H$  (see the variable G in the instant invention) results in the group (Cyc)s being some biological carrier which is disclosed by

Lauffer et al. Hence, Lauffer et al disclose contrast agents encompassed by Applicant claims 1, 5, and 6.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'D. L. Jones', with a stylized flourish extending to the right.

D. L. Jones  
Primary Examiner  
Art Unit 1616

March 17, 2005